UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

KAREN GREEN,

Plaintiff,

- against -

COVIDIEN LP,

Defendant.

ORDER

18 Civ. 2939 (PGG)

PAUL G. GARDEPHE, U.S.D.J.:

Plaintiff Karen Green brings this action against Defendant Covidien LP, asserting claims for strict products liability, negligence, breach of warranty, fraudulent misrepresentation, negligent misrepresentation, unjust enrichment, and consumer fraud. Plaintiff alleges that she suffered injuries after her physician used Defendant's Symbotex Composite Mesh (hereinafter, "Symbotex Mesh") to repair a hernia. Defendant has moved to dismiss the Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6). For the reasons stated below, Defendant's motion will be granted.

BACKGROUND

"A hernia is a medical condition caused by the penetration of fatty tissue, intestine, or organs through a weakened or compromised location in muscle [or] connective tissue." (Am. Cmplt. (Dkt. No. 14) ¶ 16) Hernias can be treated surgically, with or without the use of surgical mesh. (Id. ¶¶ 19, 29) When mesh is used, it is "introduced to the hernia site to strengthen the repair, in hopes of reducing the likelihood of recurrence." (Id. ¶ 22)

On March 4, 2016, Plaintiff underwent a laparoscopic hernia repair procedure. (Id. ¶ 49) During the procedure, Plaintiff's surgeon used the Symbotex Mesh – "designed, patented, manufactured, labeled, packaged, marketed, sold, and distributed" by Defendant – to

repair the hernia. (Id. ¶¶ 30, 49–50) On March 13, 2016, Plaintiff underwent a second surgery to investigate "complaints of abdominal pain, possible adhesions, partial small bowel obstruction[,] and infected abdominal wall[s]." (Id. ¶ 51) During this procedure, Plaintiff's "mesh was revised and adhesions[1] were taken down." (Id. ¶ 52)

Since that time, Plaintiff "has experienced and continues to experience recurring hernias . . . [a]s a direct and proximate result of the implanted mesh products [in] her body." (Id. ¶¶ 53–54)

DISCUSSION

I. MOTION TO DISMISS STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). "In considering a motion to dismiss . . . the court is to accept as true all facts alleged in the complaint," Kassner v. 2nd Ave. Delicatessen Inc., 496 F.3d 229, 237 (2d Cir. 2007) (citing Dougherty v. Town of N. Hempstead Bd. of Zoning Appeals, 282 F.3d 83, 87 (2d Cir. 2002)), and must "draw all reasonable inferences in favor of the plaintiff." Id. (citing Fernandez v. Chertoff, 471 F.3d 45, 51 (2d Cir. 2006)).

A complaint is inadequately pled "if it tenders 'naked assertion[s]' devoid of 'further factual enhancement,'" Iqbal, 556 U.S. at 678 (quoting Twombly, 550 U.S. at 557), and does not provide factual allegations sufficient "to give the defendant fair notice of what the claim is and the grounds upon which it rests." Port Dock & Stone Corp. v. Oldcastle Northeast, Inc.,

[1] An adhesion is "scar-like tissue that sticks tissues together." Hernia Surgical Mesh Implants, FDA, https://www.fda.gov/medical-devices/implants-and-prosthetics/hernia-surgical-mesh-implants (last visited May 17, 2019).

507 F.3d 117, 121 (2d Cir. 2007) (citing Twombly, 550 U.S. at 555 (quoting Conley v. Gibson, 355 U.S. 41, 47 (1957))).

Fed. R. Civ. P. 9(b) sets standards for pleading fraud claims and requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); see also In re Pfizer Inc. Sec. Litig., 584 F. Supp. 2d 621, 632–33 (S.D.N.Y. 2008) (quoting Kalnit v. Eichler, 264 F.3d 131, 138 (2d Cir. 2001)). Rule 9(b) requires a plaintiff to "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." Kottler v. Deutsche Bank AG, 607 F. Supp. 2d 447, 462 (S.D.N.Y. 2009) (quoting Stevelman v. Alias Research, Inc., 174 F.3d 79, 84 (2d Cir. 1999) (internal quotation marks and citation omitted)).

II. STRICT PRODUCTS LIABILITY

The Amended Complaint asserts strict products liability claims for defective design, defective manufacturing, and failure to warn. For the reasons stated below, these claims will be dismissed.

A. Defective Design

To state a claim for defective design, Plaintiff must allege that "(1) the product as designed posed a substantial likelihood of harm; (2) it was feasible to design the product in a safer manner; and (3) the defective design was a substantial factor in causing the plaintiff's injury." Cowan v. Costco Wholesale Corp., No. 15 Civ. 5552 (PKC), 2017 WL 59080, at *2 (E.D.N.Y. Jan. 5, 2017) (citing Simon v. Smith & Nephew, Inc., 990 F. Supp. 2d 395, 403 (S.D.N.Y. 2013)).

The Amended Complaint alleges two defects in the design of the Symbotex Mesh: First, "[m]icroporous meshes such as those made with ePFTE, including the Symbotex Mesh[],

are at a higher risk of infection and seroma formation because bacteria can survive within the smaller pores." (Am. Cmplt. (Dkt. No. 14) ¶ 60) Second, "[l]ightweight meshes, such as the Symbotex Mesh[,] are not able to adhere as strongly to the abdominal wall and cause a higher rate of recurrence." (Id.)

As an initial matter, Plaintiff concedes in her opposition brief that the Symbotex Mesh is a macroporous rather than a microporous product. (Pltf. Br. (Dkt. No. 17) at 11)[2] Accordingly, the factual predicate for Plaintiff's defective design claim is admittedly false, and this sloppy error alone requires that Plaintiff's defective design claim be dismissed. Although Plaintiff asserts in her opposition brief that Defendant's macroporous product is also defective, Plaintiff cannot use her opposition brief to amend the Amended Complaint. Lazaro v. Good Samaritan Hosp., 54 F. Supp. 2d 180, 184 (S.D.N.Y.1999) ("[I]t is axiomatic that the Complaint cannot be amended by the briefs in opposition to a motion to dismiss."). To the extent that Plaintiff also asserts that the Symbotex Mesh is a "[l]ightweight mesh," this allegation – which is not supported by any facts – is not sufficient, particularly given that Plaintiff concedes that the

[2] Although Plaintiff characterizes her reference to microporous rather than macroporous as a "typographical error," the entire premise for the defective design claim set forth in the Amended Complaint is that microporous material is more susceptible to causing bacterial infection. (Am. Cmplt. (Dkt. No. 14) ¶ 60) Plaintiff explains the "typographical error" as follows, and asserts that – fortuitously – the macroporous nature of the Symbotex Mesh also is a design defect:

> Due to a typographical error, Plaintiff mislabeled the product as microporous instead of macro-porous. However, through further and ongoing investigation, this design is inevitably worse than Plaintiff understood, due to the fact that the pores of the mesh are larger than that of the microporous structure, nerves can grow more easily into the large, "macro" pores, causing severe pain.

(Pltf. Br. (Dkt. No. 17) at 11) These new allegations set forth in Plaintiff's opposition brief cannot be considered in determining the adequacy of the Amended Complaint.

Amended Complaint addresses the wrong product. (Pltf. Br. (Dkt. No. 17) at 11 (citing Am. Cmplt. (Dkt. No. 14) ¶ 60))

Even if Plaintiff had properly characterized the nature of Defendant's product, the Amended Complaint does not adequately allege that there is a feasible alternative design for the Symbotex Mesh. Although Plaintiff states that "[a]lternative designs for hernia mesh products and/or procedures existed that were and/or are less dangerous and equally, i[f] not more, effective" (Am. Cmplt. (Dkt. No. 14) ¶ 62), this conclusory assertion is nothing more than a "[t]hreadbare recital[] of the elements of [the] cause of action." Iqbal, 556 U.S. at 678 (citing Twombly, 550 U.S. at 555). Simply asserting that a feasible alternative design exists – without pleading any supporting facts – is not sufficient to plead a defective design claim or to put Defendant on notice as to what that design might be. See id. at 698–99; see also Kennedy v. Covidien, LP, No. 118 Civ. 1907 (LTS) (KNF), 2019 WL 1429979, at *4 (S.D.N.Y. Mar. 29, 2019) (in a hernia mesh case asserting a design defect claim, "Plaintiff's conclusory allegation alluding to a safer alternative is not pleaded in sufficient detail to support a reasonable inference that there are indeed feasible alternative products").

The Amended Complaint also alleges that "[s]afer and more effective alternatives to hernia mesh exist and have existed since the introduction of hernia mesh products into the market. These include the Shouldice Repair, McVay Repair, Bassini Repair, and Desarda Repair." (Am. Cmplt. (Dkt. No. 14) ¶ 29) "However, alleging that the product should not be used at all is insufficient to satisfy the feasible alternative design element." Kennedy, 2019 WL 1429979, at *4 (citing S.F. v. Archer Daniels Midland Co., 594 Fed. App'x 11, 12–13 (2d Cir. 2014); Hilare v. DeWalt Indus. Tool Co., 54 F. Supp. 3d 223, 248 (E.D.N.Y. 2014)) (finding that

hernia repair procedures that do not use surgical mesh do not constitute a feasible alternative design in a hernia mesh defective design claim).

Although Plaintiff contends that she is not required to plead an alternative feasible design (Pltf. Br. (Dkt. No. 17) at 12), she is incorrect. "Although a plaintiff need not possess specialized scientific or technical knowledge at the pleading stage, courts have routinely dismissed strict products liability claims premised on a design defect where the plaintiff has failed to plead that it was feasible to design the product in a safer manner." Kennedy, 2019 WL 1429979, at *3 (citing DiBartolo v. Abbott Labs., 914 F. Supp. 2d 601, 622–23 (S.D.N.Y. 2012) (rejecting plaintiff's argument that a design defect claim does not require a pleading of a feasible alternative design)). Accordingly, Plaintiff's defective design claim will be dismissed.

B. Defective Manufacturing

"A manufacturing defect occurs when 'a mistake in manufacturing renders a product that is ordinarily safe dangerous so that it causes harm.'" Church Ins. Co. v. Trippe Mfg. Co., No. 04 Civ. 6111 (HB), 2005 WL 2649332, at *1 (S.D.N.Y. Oct. 17, 2005) (quoting McCarthy v. Olin Corp., 119 F.3d 148, 154 (2d Cir. 1997)). To state a claim for defective manufacturing, "the plaintiff must show [(1)] that a specific product unit was defective as a result of 'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and [(2)] that the defect was the cause of plaintiff's injury." Colon ex rel. Molina v. BIC USA, Inc., 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001) (quoting Caprara v. Chrysler Corp., 52 N.Y.2d 114, 129 (1981)). "Moreover, it is well-settled that a plaintiff may rely upon the circumstances of an accident to prove the existence of a manufacturing defect if the product did not perform as intended and the possibility of other causes has been excluded." Williamson v. Stryker Corp., No. 12 Civ. 7083 (CM), 2013 WL

3833081, at *5 (S.D.N.Y. July 23, 2013) (citing Sanchez v. Stanley–Bostitch, Inc., No. 98 Civ. 0494 (LMM), 2000 WL 968776, at *2 (S.D.N.Y. July 13, 2000)).

Plaintiff alleges that "Defendant's hernia mesh products were defective in their manufacture" and that "Defendant's hernia mesh product[s] failed to perform in their intended manner due to a flaw in the manufacturing process." (Am. Cmplt. (Dkt. No. 14) ¶¶ 58, 69) However, Plaintiff does not plead facts showing how Defendant's manufacturing process was flawed, or in what way the mesh in question deviated from Defendant's design.

Plaintiff argues, however, that the Amended Complaint provides circumstantial evidence of a manufacturing defect: "Plaintiff alleged that Defendant's product has caused her to suffer abdominal pain and recurring hernias. . . . Causing abdominal pain is not what [the Symbotex Mesh] was intended to do, which indicates that Defendant's product deviated from the manufacturer's intended process." (Pltf. Br. (Dkt. No. 17) at 13)

This is a non-sequitur. Defective manufacturing is not shown merely by proof that a consumer was injured, and by asserting that the product was not intended to injure its user. "If Plaintiff is going to rely on the circumstantial theory of liability described in New York case law, she must allege [facts] to nudge her claim above the level of speculation and into the realm of the plausible." Goldin v. Smith & Nephew, Inc., No. 12 Civ. 9217 (JPO), 2013 WL 1759575, at *3 (S.D.N.Y. Apr. 24, 2013).

Moreover, Plaintiff's alleged injuries – recurring hernias and abdominal pain – are among the complications listed on the Symbotex Mesh warning label. (Am. Cmplt. (Dkt. No. 14) ¶ 79 ("The possible complications associated with the use of [the Symbotex Mesh include] recurrence . . . [and] chronic pain. . . .")) Courts have dismissed manufacturing defect claims based on circumstantial evidence, where that evidence includes injuries that appear on the

product's warning label: "[T]he Complaint contains warnings of the conditions Plaintiff complains of, thus leading to the inference that the product was manufactured and performed as intended." Kennedy, 2019 WL 1429979, *4 (dismissing manufacturing defect claim in a hernia mesh products liability case).

Accordingly, Plaintiff's manufacturing defect claim will be dismissed.

C. Failure to Warn

To state a claim for failure to warn, "a plaintiff must demonstrate that (1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." State Farm Fire & Cas. Co. v. Nutone, Inc., 426 Fed. App'x 8, 10 (2d Cir. 2011) (citing Liriano v. Hobart Corp., 92 N.Y.2d 232, 237 (1998)). "At the motion to dismiss stage, a plaintiff must plead facts pertaining to how the warning was inadequate or insufficient." Kennedy, 2019 WL 1429979, at *5 (citing Reed v. Pfizer, Inc., 839 F. Supp. 2d 571, 575 (E.D.N.Y. 2012)).

Plaintiff alleges that Defendant's Symbotex Mesh product "contained warnings which were inadequate and insufficient to alert physicians or consumers to the dangerous risks associated with the product, including, without limitation, extreme pain, risk of malfunction, decreased efficacy, recurrent hernia, perforation of tissue and/or organs, adherence to tissue/organs, infection, nerve damage, subsequent surgeries and other complications." (Am. Cmplt. (Dkt. No. 14) ¶ 72) Plaintiff further complains that Defendant's warnings for the Symbotex Mesh were "ambiguous," "not sufficient, accurate or clear," "generic," "ineffective," and "not specifically tailored to . . . hernia mesh product[s]." (Id. ¶¶ 78, 80–81) She further alleges that she was never "warned of the 'possible complication' that actually occurred." (Id. ¶ 82)

According to the Amended Complaint, Defendant's warnings for the Symbotex Mesh read as follows: "The possible complications associated with the use of [the Symbotex Mesh] are those typically associated with surgically implanted mesh: seroma, hematoma, recurrence, fistula formation, adhesions, infection, inflammation, chronic pain, and/or allergic reactions to the components of the product." (Id. ¶ 79)

As an initial matter, the injuries that Plaintiff allegedly suffered – recurring hernias, pain, and adhesions – are included in Defendant's warnings as they are set forth in the Amended Complaint. Accordingly, Plaintiff has not alleged facts making out a failure to warn claim. Second, Plaintiff's "allegations do not include any factual content regarding . . . how the provided warnings and information failed to []accurately reflect[] reality; they do not provide a plausible basis to support an inference that [Defendant] misrepresented anything." Reed, 839 F. Supp. 2d at 576 (citing Iqbal, 556 U.S. at 677); see also Kennedy, 2019 WL 1429979, at *5 ("Plaintiff has failed to provide factual support for his conclusory assertion that Defendant's warnings did not adequately caution physicians and patients concerning the risks associated with PCOx Mesh.").

Accordingly, Plaintiff's failure to warn claim will be dismissed.

III. NEGLIGENCE

In the Amended Complaint, Plaintiff alleges that Defendant was "negligent in designing, manufacturing, and selling the hernia mesh products," and "fail[ed] to adequately warn Plaintiff and/or her physicians . . . [of the] risks associated with the hernia mesh products." (Am. Cmplt. (Dkt. No. 14) ¶¶ 87, 91)

"The New York Court of Appeals has held that claims for negligent design and design-based strict products liability should be analyzed under the same standard in products liability cases." Kennedy, 2019 WL 1429979, at *5 (citing Denny v. Ford Motor Co., 87 N.Y.2d

248, 258 (1995); Adams v. Genie Indust., Inc., 14 N.Y.3d 535, 542–43 (2010) (confirming that the standard set forth in Voss v. Black & Decker Manufacturing Co., 59 N.Y.2d 102 (1983) applies to both strict products liability and negligence claims)).

Because Plaintiff's strict products liability claims have been dismissed, her negligence claim will likewise be dismissed. See id. ("Since Plaintiff's strict products liability claim for design defect, manufacturing defect, and failure to warn have all been dismissed, his allegations in Count III that Defendant negligently designed, manufactured, and sold the PCOx Mesh must also be dismissed.").

IV. BREACH OF IMPLIED WARRANTY

The Amended Complaint alleges that "Defendant impliedly warranted to Plaintiff and all others similarly situated that their hernia mesh products were reasonably fit for [their] intended use," but that the Symbotex Mesh was "defective in [its] manufacture or design and w[as] therefore, not fit for its intended use and was not designed, manufactured, or sold in accordance with good design, engineering, and industry standards." (Am. Cmplt. (Dkt. No. 14) ¶¶ 93–94)

"The implied warranty of merchantability is a guarantee by the seller that its goods are fit for the intended purpose for which they are used and that they will pass in the trade without objection." Caronia v. Philip Morris USA, Inc., 715 F.3d 417, 433 (2d Cir. 2013) (citing Saratoga Spa & Bath, Inc. v. Beeche Systems Corp., 230 A.D.2d 326, 330 (3d Dept. 1997)). "This standard does not require that the goods be perfect, or that they fulfill [a] buyer's every expectation; it requires only that the goods sold be of a minimal level of quality." Morrison v. Hoffmann-La Roche, Inc., No. 14 Civ. 4476 (DLI) (RML), 2016 WL 5678546, at *10–11 (E.D.N.Y. Sept. 29, 2016) (citing Caronia, 715 F.3d at 433–34).

> "The inquiry focuses on the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manners. The cause of action is one involving true 'strict' liability, since recovery may be had upon a showing that the product was not minimally safe for its expected purpose – without regard to the feasibility of alternative designs or the manufacturer's 'reasonableness' in marketing it in that unsafe condition."

Caronia, 715 F.3d at 434 (quoting Denny, 87 N.Y.2d at 258–59) (emphasis omitted).

"[T]he New York Court of Appeals has taken care to distinguish this merchantability-related strict liability from the liability that is more typically associated with claims for defective products."[3] Id. Accordingly, "Plaintiff's ability to recover under his breach of implied warranty claim is not affected by the feasibility of making the product safer. . . ." Porrazzo v. Bumble Bee Foods, LLC, 822 F. Supp. 2d 406, 422 (S.D.N.Y. 2011).

"To the extent that Plaintiff's breach of implied warranty claim is based on design defect, under New York law such a claim 'requires proof of the following three elements: (1) that the product was defectively designed or manufactured; (2) that the defect existed when the manufacturer delivered it to the purchaser or user; and (3) that the defect is the proximate cause of the accident.'" Morrison, 2016 WL 5678546, at *10–11 (quoting Simon, 990 F. Supp. 2d at 407).

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[3] As a result,

> "the core element of 'defect' is subtly different in the two causes of action." Denny, 87 N.Y.2d at 256. In products liability cases, the New York courts will inquire whether, "if the design defect were known at the time of manufacture, a reasonable person would conclude that the utility of the product did not outweigh the risk inherent in marketing a product designed in that manner." Id. at 257 (internal quotation marks omitted). By contrast, "the UCC's concept of a 'defective' product requires an inquiry only into whether the product in question was fit for the ordinary purposes for which such goods are used." Id. at 258 (internal quotation marks omitted). Products liability's "negligence-like risk/utility approach is foreign to the realm of contract law." Id. at 262.

Caronia, 715 F.3d at 434.

Here, the Amended Complaint alleges that the Symbotex Mesh is defectively designed because it is microporous and constructed of lightweight mesh. (Am. Cmplt. (Dkt. No. 14) ¶ 60) As discussed above, Plaintiff concedes that in the Amended Complaint it "mislabeled [Defendant's] product as microporous instead of macro-porous." (Pltf. Br. (Dkt. No. 17) at 11) In other words, Plaintiff concedes that the Amended Complaint describes the wrong product. To the extent that Plaintiff also asserts that the Symbotex Mesh is a "lightweight mesh," this allegation – which is not supported by any facts – is not sufficient, particularly given that Plaintiff concedes that the Amended Complaint addresses the wrong product. (Am. Cmplt. (Dkt. No. 14) ¶ 60)

Accordingly, Plaintiff's claim for breach of implied warranty will be dismissed.

V. MISREPRESENTATION

The Amended Complaint includes claims for fraudulent and negligent misrepresentation. Defendant contends that these claims are insufficient, because they must – and do not – meet the particularity standards of Fed. R. Civ. P. 9(b). (Def. Br. (Dkt. No. 19) at 12)

"To state a claim for fraudulent misrepresentation under New York law 'a plaintiff must show that (1) the defendant made a material false representation, (2) the defendant intended to defraud the plaintiff thereby, (3) the plaintiff reasonably relied upon the representation, and (4) the plaintiff suffered damage as a result of such reliance.'" Eternity Glob. Master Fund Ltd. v. Morgan Guar. Tr. Co. of N.Y., 375 F.3d 168, 186–87 (2d Cir. 2004) (quoting Banque Arabe et Internationale D'Investissement v. Md. Nat'l Bank, 57 F.3d 146, 153 (2d Cir. 1995)). "'Under New York law, the elements for a negligent misrepresentation claim are that (1) the defendant had a duty, as a result of a special relationship, to give correct information; (2) the defendant made a false representation that he or she should have known was

incorrect; (3) the information supplied in the representation was known by the defendant to be desired by the plaintiff for a serious purpose; (4) the plaintiff intended to rely and act upon it; and (5) the plaintiff reasonably relied on it to his or her detriment.'" Fisher v. APP Pharm., LLC, 783 F. Supp. 2d 424, 432 (S.D.N.Y. 2011) (quoting Hydro Investors, Inc. v. Trafalgar Power Inc., 227 F.3d 8, 20 (2d Cir. 2000)).

Here, Plaintiff does not dispute that Rule 9(b) applies to both her fraudulent and negligent misrepresentations claims. According to the Second Circuit, however, "Rule 9(b) may or may not apply to a state law claim for negligent misrepresentation." Eternity Glob. Master Fund Ltd., 375 F.3d at 188. The issue turns on whether the negligent misrepresentation claim sounds in fraud. Tyman v. Pfizer, Inc., No. 16 Civ. 6941 (LTS) (BCM), 2017 WL 6988936, at *8 (S.D.N.Y. Dec. 27, 2017), report and recommendation adopted, 2018 WL 481890 (S.D.N.Y. Jan. 18, 2018) (Rule 9(b) "must be applied where 'the claim sounds in fraud'") (quoting Riker v. Premier Capital, LLC, No. 15 Civ. 8293, 2016 WL 5334980, at *5 (S.D.N.Y. Sept. 22, 2016)); Woori Bank v. RBS Sec., Inc., 910 F. Supp. 2d 697, 705 (S.D.N.Y. 2012) ("District courts in this Circuit have concluded that the Rule is applicable to negligent misrepresentation claims that are premised on fraudulent conduct.").

This Court concludes that the Amended Complaint's negligent misrepresentation claim sounds in fraud. As an initial matter, the Amended Complaint alleges that "Defendant made misrepresentations of material fact from 2013 to present to Plaintiff and her physicians[] to induce them to use [the Symbotex Mesh] for hernia repair." (Am. Cmplt. (Dkt. No. 14) ¶ 97) According to Plaintiff, these misrepresentations involved, inter alia, a failure to disclose known risks and dangers associated with Defendant's product. (Id. ¶¶ 97–126) While these allegations are set forth in the Amended Complaint's fraudulent misrepresentation claim, they are

incorporated by reference in the negligent misrepresentation claim. (Id. ¶ 127) The negligent misrepresentation claim goes on to allege that Defendant knowingly made false representations concerning the safety of its Symbotex Mesh product, including by knowingly "fail[ing] to accurately communicate . . . risks associated with their product[]," and by "intentionally conceal[ing] the truth regarding the high risk of the product's unreasonable, dangerous, and adverse side effects." (Id. ¶¶ 130–31) These allegations clearly sound in fraud. Accordingly, Rule 9(b) applies to both Plaintiff's fraudulent and negligent misrepresentation claims.

To satisfy the particularity requirement of Rule 9(b), a claim must "(1) detail the statements (or omissions) that the plaintiff contends are fraudulent, (2) identify the speaker, (3) state where and when the statements (or omissions) were made, and (4) explain why the statements (or omissions) are fraudulent." Harsco Corp. v. Segui, 91 F.3d 337, 347 (2d Cir. 1996) (citing Shields v. Citytrust Bancorp., Inc., 25 F.3d 1124, 1128 (2d Cir.1994); Ouaknine v. MacFarlane, 897 F.2d 75, 79 (2d Cir.1990). "In this Circuit, a complaint may establish the requisite 'strong inference' of fraudulent intent either (a) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness, or (b) by alleging facts to show that defendants had both motive and opportunity to commit fraud." Stevelman, 174 F.3d at 84 (citing Chill, 101 F.3d at 267; Shields, 25 F.3d at 1128).

Here, as noted above, the Amended Complaint alleges that Defendant "made misrepresentations of material fact from 2013 to present to Plaintiff and her physicians, to induce them to use [the Symbotex Mesh] for hernia repair." (Am. Cmplt. (Dkt. No. 14) ¶ 97) These misrepresentations allegedly appeared in – or were omitted from – Defendant's website, brochures, advertisements, promotional materials, and "literature distributed to the medical community." (Id. ¶¶ 97–108) According to Plaintiff, Defendant failed to disclose the known

risks of the Symbotex Mesh, and falsely represented that the Symbotex Mesh "had been adequately tested in clinical trials and [was] found to be safe and effective." (Id. ¶¶ 98, 100-02) Defendant allegedly made these misrepresentations "intentionally, willfully, wantonly, and with reckless disregard[] and depraved indifference for the safety and well-being of the users of [its] product, including Plaintiff." (Id. ¶ 122)

Although Plaintiff alleges that a number of misrepresentations appeared on Defendant's website, and in product brochures and videos, Plaintiff does not quote or describe the alleged misrepresentations. Instead, the Amended Complaint simply offers web addresses for these materials. However, all but one of the web addresses listed in the Amended Complaint lead to the same error message: "THE REQUESTED URL . . . WAS NOT FOUND ON OUR SERVER." Accordingly, Plaintiff has not adequately identified the false statements and omissions associated with these web pages. Indeed, the Court does not know what the alleged misrepresentations and omissions are.

As to the one web address that is functional – https://www.medtronic.com/covidien/en-us/products/hernia-repair/symbotex-composite-mesh.html (see id. ¶¶ 37, 97(c)) – it is not enough for Plaintiff to allege that a website generally misrepresented the Symbotex Mesh. Rather, "Plaintiff[] must specify the exact statements [she] claim[s] were fraudulent (i.e., quote them)," or describe the omissions with particularity. Williamson, 2013 WL 3833081, at *12.

The Amended Complaint also alleges that Defendant misrepresented the Symbotex Mesh in, inter alia, "reports, press releases, advertising campaigns, print advertisements, commercial media[,] . . . 'Dear Doctor' letters, and 'Medical Information Letters,'" as well as during events hosted for medical professionals. (Am. Cmplt. (Dkt. No. 14)

¶¶ 103, 108–09) Again, Plaintiff does not quote these misrepresentations or otherwise identify them. Accordingly, any alleged misrepresentations in these materials are not adequately identified in the Amended Complaint.

The Amended Complaint does cite the following statements: "'[The Symbotex Mesh] provides surgeons improved ease of use, and optimal performance to minimize visceral tissue attachments, for meeting hernia repair solution needs'"; "'[the Symbotex Mesh] is designed to match the surgeon's demands for ease of handling, operative efficiency, and versatility'"; and "[the Symbotex Mesh] is advertised as having the following features[:] '[s]mart design,' '[s]mart [h]andling,' and '[s]mart [r]epair.'" (Id. ¶¶ 36, 43, 97(b)) However, the Amended Complaint does not explain why these statements are false and misleading.

Plaintiff also cites a "poorly provided warning" in one of Defendant's promotional brochures: "The possible complications associated with the use of [the Symbotex Mesh] are those typically associated with surgically implanted mesh: seroma, hematoma, recurrence, fistula formation, adhesions, infection, inflammation, chronic pain, and/or allergic reactions to the components of the product." (Id. ¶ 79) The Amended Complaint alleges that this warning is "very limited and inadequate" and omits known risks of using the Symbotex Mesh. (Id. ¶¶ 97(d), 98, 100, 103) Plaintiff does not explain why Defendant's warning is inadequate, however. Indeed, of the "crucial risks" that Plaintiff claims were omitted from Defendant's warning (id. ¶ 98), most of these risks are, in fact, listed in Defendant's warning – including the injuries that Plaintiff actually suffered. See Kennedy, 2019 WL 1429979, at *7 ("Absent from these allegations is any factual basis for Plaintiff's conclusion that the representations made by the Defendant were false or misleading. In fact, the advertising material incorporated into the Complaint appears to have disclosed the risks of the conditions that

Plaintiff has allegedly suffered. Plaintiff has thus failed to identify false statements and demonstrate why the statements were fraudulent."). To the extent that any alleged risk is not addressed in Defendant's warning, the Amended Complaint "lacks any showing that the alleged omissions were made with an intent to deceive." Perez v. B. Braun Med., Inc., No. 17 Civ. 8512 (LLS), 2018 WL 2316334, at *6 (S.D.N.Y. May 9, 2018).

Finally, Plaintiff alleges that Defendant misrepresented that the Symbotex Mesh "had been adequately tested in clinical trials and [was] found to be safe and effective." (Am. Cmplt. (Dkt. No. 14) ¶ 101) Plaintiff does not identify any statement containing this alleged misrepresentation, however.

In sum, Plaintiff has not adequately identified Defendant's alleged misrepresentations, explained why they are fraudulent, and/or shown that Defendant acted with intent to deceive. Accordingly, Plaintiff's fraudulent and negligent misrepresentation claims are not pled with the particularity required by Rule 9(b) and will be dismissed.

VI. UNJUST ENRICHMENT

"To state a claim for unjust enrichment under New York law, a plaintiff must allege that '(1) the defendant was enriched, (2) at the expense of the plaintiff, and (3) . . . it would be inequitable to permit the defendant to retain that which is claimed by the plaintiff.'" Koenig v. Boulder Brands, Inc., 995 F. Supp. 2d 274, 290 (S.D.N.Y. 2014) (quoting Baron v. Pfizer, Inc., 42 A.D.3d 627, 629 (2007) (citing Clifford R. Gray, Inc. v. LeChase Constr. Servs., LLC, 31 A.D.3d 983, 988, (2006))). However, "an unjust enrichment claim cannot survive 'where it simply duplicates, or replaces, a conventional contract or tort claim.'" Id. (quoting Corsello v. Verizon New York, Inc., 18 N.Y.3d 777, 790–91 (2012); citing Ebin v. Kangadis Food Inc., No. 13 Civ. 2311 (JSR), 2013 WL 6504547, at *7 (S.D.N.Y. Dec. 11, 2013)). Rather, this claim "'is available only in unusual situations when, though the defendant has not breached a

contract nor committed a recognized tort, circumstances create an equitable obligation running from the defendant to the plaintiff.'" Weisblum v. Prophase Labs, Inc., 88 F. Supp. 3d 283, 296–97 (S.D.N.Y. 2015) (quoting Corsello, 18 N.Y.3d at 790; citing Samiento v. World Yacht Inc., 10 N.Y.3d 70, 81 (2008)).

Here, "Plaintiff['s] unjust enrichment claim is based on the same allegations as those set forth in support of [her] other claims, and Plaintiff [has] not shown how [her] unjust enrichment claim differs from [her] other claims." Greene v. Gerber Prod. Co., 262 F. Supp. 3d 38, 77 (E.D.N.Y. 2017). "Although a plaintiff 'may plead unjust enrichment in the alternative to [her] other claims,' the unjust enrichment claim will not survive a motion to dismiss where the plaintiff 'fail[s] to explain how [it] is not merely duplicative of [her] other causes of action.'" Tyman, 2017 WL 6988936, at *20 (quoting Cont'l Indus. Grp., Inc. v. Altunkilic, 14 Civ. 790 (AT) (JLC), 2017 WL 2895933, at *14 (S.D.N.Y. July 7, 2017); Nelson v. MillerCoors, LLC, 15 Civ. 7082 (WFK) (RML), 2017 WL 1403343, at *9 (E.D.N.Y. Mar. 31, 2017)). Accordingly, Plaintiff's unjust enrichment claim will be dismissed. See Weisblum, 88 F. Supp. 3d at 297 ("[B]ecause [Plaintiff] has not shown that his unjust enrichment claim differs from his contract and tort claims, it must be dismissed.").

VII. CONSUMER FRAUD

"[New York General Business Law ("GBL")] [S]ection 349 prohibits '[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state.' GBL [S]ection 350 prohibits '[f]alse advertising in the conduct of any business, trade[,] or commerce or in the furnishing of any service in this state.'" Greene, 262 F. Supp. 3d at 67 (citing N.Y. Gen. Bus. Law §§ 349–50). "Under either section the plaintiff must allege that the defendant has engaged in '(1) consumer-oriented conduct that is (2) materially misleading and that (3) plaintiff suffered injury as a result of the allegedly deceptive act or

practice.'" Kennedy, 2019 WL 1429979, at *7 (quoting Orlander v. Staples, Inc., 802 F.3d 282, 300 (2d Cir. 2015); citing Koch v. Acker, Merrall & Condit Co., 18 N.Y.3d 940, 941 (2012)). "Claims under GBL [S]ections 349 and 350 are not subject to the pleading-with-particularity requirements of Rule 9(b)." Greene, 262 F. Supp. 3d at 67 (citing Schwartzco Enters. LLC v. TMH Mgmt., LLC, 60 F. Supp. 3d 331, 359 (E.D.N.Y. 2014); Pelman ex rel. Pelman v. McDonald's Corp., 396 F.3d 508, 511 (2d Cir. 2005); Leonard v. Abbott Labs., Inc., No. 10 Civ. 4676 (ADS) (WDW), 2012 WL 764199, at *19). However, "a plaintiff still must show that the alleged deceptive acts would mislead a reasonable consumer acting reasonably under the circumstances." Kennedy, 2019 WL 1429979, at *7 (citing Stutman v. Chemical Bank, 95 N.Y.2d 24, 28–29 (2000)).

Here, the Amended Complaint asserts that "Defendant engaged in consumer-oriented, commercial conduct by selling and advertising the subject product[;] Defendant misrepresented and omitted material information regarding the subject product by failing to disclose known risks"; and Plaintiff suffered damages as a result. (Am. Cmplt. (Dkt. No. 14) ¶¶ 144–46) The Amended Complaint does not quote or attach any consumer-oriented marketing material, however, nor does it explain how that material misrepresented the risks of using the Symbotex Mesh. Accordingly, Plaintiff's allegations amount to no more than a "[t]hreadbare recital[] of the elements of [the] cause of action," and her claims under the General Business Law will be dismissed. Iqbal, 556 U.S. at 678 (citing Twombly, 550 U.S. at 555).

VIII. PUNITIVE DAMAGES

"While plaintiff is entitled to include in her prayer for relief a request that she be awarded punitive damages in the event she proves the requisite degree of culpability on her causes of action[,] . . . a claim for punitive damages may not be maintained as a separate cause of

action." La Porta v. Alacra, Inc., 142 A.D.3d 851, 853 (1st Dept. 2016) (citing Rocanova v. Equitable Life Assur. Socy. of U.S., 83 N.Y.2d 603, 616–617 (1994)).

Accordingly, to the extent the Amended Complaint presents a claim for punitive damages as a separate cause of action, that claim will be dismissed.

IX. LEAVE TO AMEND

"[I]t is often appropriate for a district court, when granting a motion to dismiss for failure to state a claim, to give the plaintiff leave to file an amended complaint." Van Buskirk v. N.Y. Times Co., 325 F.3d 87, 91 (2d Cir. 2003) (citing Branum v. Clark, 927 F.2d 698, 705 (2d Cir. 1991)). "Leave to amend should be freely granted, but the district court has the discretion to deny leave if there is a good reason for it, such as futility, bad faith, undue delay, or undue prejudice to the opposing party." Jin v. Metro. Life Ins. Co., 310 F.3d 84, 101 (2d Cir. 2002) (citing Foman v. Davis, 371 U.S. 178, 182 (1962); Koehler v. Bank of Berm. (N.Y.) Ltd., 209 F.3d 130, 138 (2d Cir. 2000)).

Here, Defendant has not pointed to any compelling reason why leave to amend should be denied. Accordingly, Plaintiff is granted leave to amend. Any Second Amended Complaint will be filed by **September 20, 2019**.

CONCLUSION

For the reasons stated above, Defendants' motion to dismiss is granted. The Clerk of Court is directed to terminate the motion (Dkt. No. 18).

Dated: New York, New York
August 30, 2019

SO ORDERED.

Paul G. Gardephe
United States District Judge